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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,020	06/28/2005	Kenji Fujii	Q88147	4034

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EXAMINER	
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12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,020	FUJII ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *24 Jul 08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-37 are presented for examination.

Applicant is notified that the finality of the previous Office Action dated July 9, 2008 is hereby withdrawn. The after-final amendment filed September 9, 2008 has been entered into the record and prosecution of the present application has been reopened.

Applicant's after-final amendment filed September 9, 2008 has been received and entered into the instant application.

Applicant's Information Disclosure Statement (IDS) filed July 24, 2008 has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (one page total), the Examiner has considered the cited references.

Claims 28-37 remain pending and under examination.

Applicant's arguments and amendments, filed September 9, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Present claim 30 is directed to the method of claim 28 or 29, wherein the coenzyme Q is coenzyme Q10.

In particular, the antecedent basis for the phrase "the coenzyme Q" as recited in present claim 30

is unclear because the claim fails to specify whether the phrase "the coenzyme Q" limits the reduced coenzyme Q or the oxidized coenzyme Q or both. For this reason, the claim fails to clearly, deliberately and precisely set forth the type of coenzyme Q to be used in the instantly claimed method(s). Accordingly, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the scope of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

For the purposes of examination, the claim will be interpreted to read upon the use of coenzyme Q10 in either a reduced or an oxidized form.

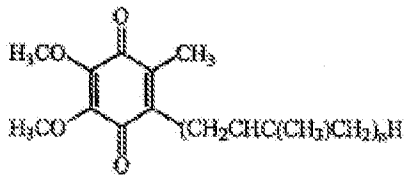
Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

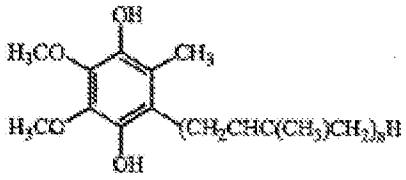
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hidaka et al. (CA 2406570 A1, October 2002; cited by Applicant) as evidenced by Merriam-Webster Collegiate Dictionary (1996; p.424).

Hidaka et al. teaches a composition for dermal application (i.e., "applied to skin" as in instant claim 31; p.7, l.27-32) containing as the active ingredient oxidized coenzyme Q of the formula



, wherein n is an integer of from 1 to 12 and/or reduced coenzyme Q



of the formula , wherein n is also an integer of from 1 to 12, wherein coenzyme Q10 is particularly preferred as the oxidized and/or reduced form (p.7, l.20-26), wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.01-99% by weight of the total composition (abstract). Hidaka et al. further teaches a method for treating skin diseases, such as, *inter alia*, atopic dermatitis, wounds, burns, psoriasis, skin ulcer, etc. (p.8, l.9-19), comprising applying the dermal composition to patients with skin diseases, and additionally discloses that the composition may be intended for application to humans (i.e., a vertebrate, as well as mammal, as in instant claims 32-33), pets, domestic animals, birds, dogs and/or cats (p.7, l.27-32).

Merriam-Webster is cited as evidence to define the term "fatigue" as used in the instant claims as "a weariness or exhaustion from labor, exertion or stress" (p.424).

In view of the fact that the term “fatigue” is defined as a weariness or exhaustion from, *inter alia*, stress, and further in view of the fact that any disease or disorder, including the skin diseases (such as, e.g., burns) disclosed in Hidaka et al., causes bodily stress, it necessarily follows that the subject treated via the method disclosed in Hidaka et al. (i.e., a patient suffering from a skin disease) is also concomitantly in a state of fatigue as a result of the bodily stress caused by suffering from the various disclosed skin ailments. Thus, the subject of Hidaka et al. meets the subject required by the instant claims (i.e., “animals in the state of fatigue”; see, e.g., instant claims 28-29) and, therefore, the coenzyme Q combination composition inherently possesses the same fatigue reducing effects when administered to the patient if Hidaka et al., whether recognized by the patentee or not, because products of identical chemical composition cannot exert mutually exclusive properties when used in the same manner (i.e., same composition, same host, same amount, etc.) under the same circumstances. In other words, if the prior art

teaches the identical chemical or physical structure of the composition (i.e., same agents, same amounts, etc.) for use in the same subject (i.e., in this case, an animal in a state of fatigue), the fatigue-reducing property that Applicant discloses and/or claims is necessarily present. Please reference MPEP §2112.

Furthermore, with regard to instant claim 35, which is directed to the administration of the claimed coenzyme formulation to "middle aged or older persons", Hidaka et al. broadly teaches the use of the disclosed coenzyme Q formulation for use in humans *per se* and, thus, places the treatment of any human at any stage of development (i.e., "young", "middle aged" or "older"), within the possession of the public.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

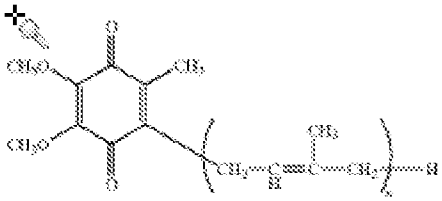
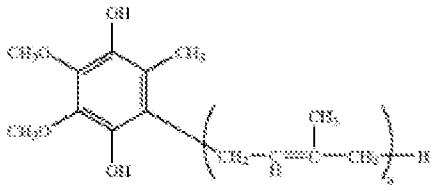
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (WO 2002/092067; 2002), citing to U.S. Patent Application Publication No. 2004/0115181 (2004) for

an English translation, in view of Staub et al. ("Fatigue after Stroke: A Major but Neglected Issue", *Cerebrovascular Diseases,* 2001; 12(2):75-81).

For the purposes of examination, U.S. Patent Application Publication No. 2004/0115181 A1 to Fujii et al. (Published June 17, 2004) will be relied upon for an English translation of the WO 2002/092067 reference relied upon as the basis for the present rejection. The '181 publication is the publication under 35 U.S.C. 122(b) of U.S. Patent Application No. 10/476,208, which is the U.S. National Stage (371) entry of PCT/JP02/04476, of which WO 2002/092067 is the International WIPO Publication of the same and is, thus, expected to contain the same subject matter. Reliance upon this document is in accordance with the MPEP at §901.05, which states, "It is possible to cite a foreign language specification as a reference, while at the same time citing an English language version of the specification with a later date as a convenient translation if the latter is in fact a translation." For clarity of the record, Applicant is notified that the page and paragraph numbers cited herein the instant rejection refer to the '181 publication and not the '067 publication.

Fujii et al. teaches a composition for transmucosal administration comprising an oxidized coenzyme Q of the formula  , wherein n represents an integer of 1 to 12, and/or reduced coenzyme Q of the formula  , wherein n also represents an integer or 1 to 12 (p.1, para.[0007-0009]), wherein coenzyme Q with 10 side chain repeating units (i.e., an oxidized coenzyme Q10 and reduced coenzyme Q10) are preferably used (p.2, para.[0016]),

wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.0001-99% by weight of the total composition (p.1, para.[0010]). Fujii et al. further teaches a method for treating, *inter alia*, cerebral infarction, heart failure, etc. (p.2, para.[0023]) comprising applying the composition for transmucosal administration to human or animal mucosa with a disease (p.5, cl.18), wherein the composition may be used in humans (i.e., a vertebrate, as well as mammal, as in instant claims 32-33), including aged persons (as in instant claim 35; p.4, para.[0042]), dogs, cats, race horses, cows, horses, pigs, rabbits, rats, mice, birds and the like (p.1, para.[0010]).

Fujii et al. fails to specifically teach the treatment of animals in a state of fatigue for reducing fatigues (see, e.g., instant claims 28-29), particularly wherein the fatigue is physical exhaustion during or after sickness (claim 36).

Staub et al. teaches that, after stroke, patients frequently complain of disabling fatigue (p.76, col.2, para.4) and further describes a study of 88 subjects (between 27 and 91 years of age) selected among 181 patients admitted with acute stroke and found that 68% of stroke patients reported fatigue (defined as a physical tiredness and lack of energy) (p.77, col.1, para.2) versus control subjects.

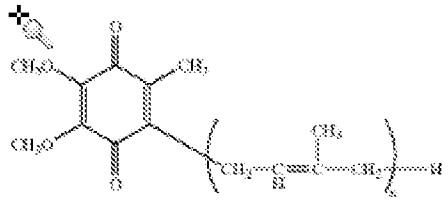
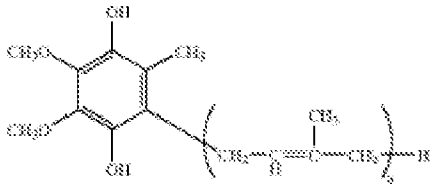
In view of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the disclosed coenzyme Q formulation of Fujii et al. would have been reasonably expected to exert the same or substantially similar efficacy in the reduction of fatigue in a patient in a state of fatigue because: (1) the composition of Fujii et al. was known to have efficacy in treating patients that have suffered from cerebral infarction (i.e., stroke) and (2) a significant proportion of patients that have had cerebral infarction suffer subsequently from profound fatigue. Fujii et al. provides the clear teaching that the instantly claimed coenzyme Q formulation (i.e., comprising an oxidized and reduced form of coenzyme Q) is, in fact, effective for treating all cerebral infarction patients, i.e., 100% of patients with cerebral infarction, without exclusion. Of this entire population of cerebral infarct patients, Staub et al. provides the factual extrinsic evidence demonstrating that a subpopulation of

cerebral infarct patients also suffers concomitantly from profound poststroke fatigue. Accordingly, the suggestion of Fujii et al. to use the claimed coenzyme Q formulation for treating any cerebral infarct patient is a clearly suggestion to use it in any subpopulation of cerebral infarct patients, such as those patients also suffering from profound poststroke fatigue, with the reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of cerebral infarct (i.e., stroke) patients *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed coenzyme Q formulation has in reducing fatigue in an animal in a state of fatigue must necessarily be present in the method disclosed by Fujii et al., absent factual evidence to the contrary.

Claims 28-30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (WO 2002/092067; 2002), citing to U.S. Patent Application Publication No. 2004/0115181 (2004) for an English translation, in view of Wilson et al. ("Exertional Fatigue Due to Skeletal Muscle Dysfunction in Patients with Heart Failure", *Circulation*, 1993; 87:470-475).

For the purposes of examination, U.S. Patent Application Publication No. 2004/0115181 A1 to Fujii et al. (Published June 17, 2004) will be relied upon for an English translation of the WO 2002/092067 reference relied upon as the basis for the present rejection. The '181 publication is the publication under 35 U.S.C. 122(b) of U.S. Patent Application No. 10/476,208, which is the U.S. National Stage (371) entry of PCT/JP02/04476, of which WO 2002/092067 is the International WIPO Publication of the same and is, thus, expected to contain the same subject matter. Reliance upon this document is in accordance with the MPEP at §901.05, which states, "It is possible to cite a foreign language specification as a reference, while at the same time citing an English language version of the specification with a later date as a convenient translation if the latter is in fact a translation." For clarity of the record, Applicant is

notified that the page and paragraph numbers cited herein the instant rejection refer to the '181 publication and not the '067 publication.

Fujii et al. teaches a composition for transmucosal administration comprising an oxidized coenzyme Q of the formula  , wherein n represents an integer of 1 to 12, and/or reduced coenzyme Q of the formula  , wherein n also represents an integer or 1 to 12 (p.1, para.[0007-0009]), wherein coenzyme Q with 10 side chain repeating units (i.e., an oxidized coenzyme Q10 and reduced coenzyme Q10) are preferably used (p.2, para.[0016]), wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.0001-99% by weight of the total composition (p.1, para.[0010]). Fujii et al. further teaches a method for treating, *inter alia*, cerebral infarction, heart failure, etc. (p.2, para.[0023]) comprising applying the composition for transmucosal administration to human or animal mucosa with a disease (p.5, cl.18), wherein the composition may be used in humans (i.e., a vertebrate, as well as mammal, as in instant claims 32-33), including aged persons (as in instant claim 35; p.4, para.[0042]), dogs, cats, race horses, cows, horses, pigs, rabbits, rats, mice, birds and the like (p.1, para.[0010]).

Fujii et al. fails to specifically teach the treatment of animals in a state of fatigue for reducing fatigues (see, e.g., instant claims 28-29), particularly wherein the fatigue is muscle fatigue (claim 37).

Wilson et al. teaches that patients with heart failure are frequently limited by exertional fatigue during both normal daily activities and maximal exercise testing and further describes a study of 34

patients with heart failure subjected to exercise for determining whether exertional fatigue is due to skeletal muscle dysfunction or reduced muscle flow (abstract). Wilson et al. teaches that all of the studied patients terminated exercise due to leg fatigue and concluded that a substantial percentage of patients with chronic heart failure develop exertional fatigue as a result of skeletal muscle dysfunction (abstract).

In view of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the disclosed coenzyme Q formulation of Fujii et al. would have been reasonably expected to exert the same or substantially similar efficacy in the reduction of fatigue in a patient in a state of fatigue because: (1) the composition of Fujii et al. was known to have efficacy in treating patients that have suffered from heart failure and (2) a significant proportion of patients that have heart failure suffer from concomitant exertional (muscle) fatigue upon exercise and normal activities. Fujii et al. provides the clear teaching that the instantly claimed coenzyme Q formulation (i.e., comprising an oxidized and reduced form of coenzyme Q) is, in fact, effective for treating all heart failure patients, i.e., 100% of patients with heart failure, without exclusion. Of this entire population of heart failure patients, Wilson et al. provides the factual extrinsic evidence demonstrating that a subpopulation of heart failure patients also suffers concomitantly from concomitant exertional (muscle) fatigue (i.e., which meets Applicant's instant limitation directed to "physical exhaustion during…sickness" which, in this case, would be heart failure). Accordingly, the suggestion of Fujii et al. to use the claimed coenzyme Q formulation for treating any heart failure patient is a clearly suggestion to use it in any subpopulation of heart failure patients, such as those patients also suffering from concomitant exertional (muscle) fatigue, with the reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of heart failure patients *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed coenzyme Q formulation has in reducing fatigue in an animal in a state of fatigue must

necessarily be present in the method disclosed by Fujii et al., absent factual evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-30 and 32-35 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over, alternatively, claims 18-19 of U.S. Patent Application No. 10/275,882; claims 6 and 15-28 of U.S. Patent Application No. 11/029,493; claims 1-18 of U.S. Patent Application No. 11/315,201; or claims 13-24 of U.S. Patent Application No. 11/909,966, each in view of Merriam-Webster Collegiate Dictionary (1996; p.424).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

Each of the copending claims specifies the treatment of various ailments, disorders, diseases or conditions (e.g., the '882 application is directed to the treatment of skin diseases) in patients suffering from such ailments, disorders, diseases or conditions comprising administering a composition of a

reduced coenzyme Q compound of a formula identical to that claimed as instant formula (1) that may optionally also be administered in combination with an oxidized coenzyme Q compound of a formula identical to that claimed as instant formula (2), wherein such formulas clearly provides for the use of reduced or oxidized coenzyme Q10, since the copending formulas provide for n to be from 1-12, and further wherein the subjects to be treated include mammals, such as humans, and patients *per se*.

Merriam-Webster is cited as evidence to define the term "fatigue" as used in the instant claims as "a weariness or exhaustion from labor, exertion or stress" (p.424).

In view of the fact that the term “fatigue” is defined as a weariness or exhaustion from, *inter alia*, stress, and further in view of the fact that any disease or disorder, including the various conditions disclosed in the copending claims (e.g., skin diseases, oxidative stress, symptoms of aging, etc.), cause bodily stress, it necessarily follows that the subject(s) treated via the method(s) disclosed in the copending claims (e.g., a patient suffering from skin disease, oxidative stress, aging, etc.) is also concomitantly in a state of fatigue as a result of the bodily stress caused by suffering from the disclosed ailments. Thus, the subject(s) of the copending claims meets the subject required by the instant claims (i.e., “animals in the state of fatigue”; see, e.g., instant claims 28-29) and, therefore, the coenzyme Q composition must necessarily possess the same fatigue reducing effects when administered to the subject(s) of the copending claims, whether recognized by the applicant or not, because products of identical chemical composition cannot exert mutually exclusive properties when used in the same manner (i.e., same composition, same host, same amount, etc.) under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same agents, same amounts, etc.) for use in the same subject (i.e., in this case, an animal in a state of fatigue), the fatigue-reducing property that Applicant discloses and/or claims is necessarily present. Please reference MPEP §2112.

Accordingly, rejection of claims 28-30 and 32-35 is proper over claims 18-19 of U.S. Patent Application No. 10/275,882; claims 6 and 15-28 of U.S. Patent Application No. 11/029,493; claims 1-18

of U.S. Patent Application No. 11/315,201; or claims 13-24 of U.S. Patent Application No. 11/909,966, as claiming obvious and unpatentable variants thereof.

Claims 28, 30 and 32-33 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 10-19 of U.S. Patent Application No. 11/596,059.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are anticipated by the copending claims.

The claims of the '059 application are directed to a method for treating fatigue in a mammal in a fatigued state by administering an effective dose of an anti-fatigue composition that comprises reduced coenzyme Q of a formula identical to that claimed as instant formula (1) and carnitine, wherein the coenzyme Q may be coenzyme Q10.

Accordingly, rejection of claims 28, 30 and 32-33 is proper over claims 6 and 10-19 of U.S. Patent Application No. 11/596,059 as claiming obvious and unpatentable variants thereof.

Claims 28, 30 and 32-35 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12 of U.S. Patent Application No. 10/505,523, in view of Merriam-Webster Collegiate Dictionary (1996; p.424).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are

not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

The claims of the '523 application are directed to a method for controlling blood glucose or for treating diabetes in a diabetes patient or a person having an abnormal glucose tolerance, comprising the administration of a composition comprising a reduced coenzyme Q of a formula identical to that claimed as instant formula (1), wherein such a formula clearly provides for the use of reduced coenzyme Q10, since the copending formula provides for n to be from 1-12.

Merriam-Webster is cited as evidence to define the term "fatigue" as used in the instant claims as "a weariness or exhaustion from labor, exertion or stress" (p.424).

In view of the fact that the term "fatigue" is defined as a weariness or exhaustion from, *inter alia*, stress, and further in view of the fact that any disease or disorder, including the diabetic condition disclosed in the copending claims, causes bodily stress, it necessarily follows that the subject(s) treated via the method(s) disclosed in the patented claims (e.g., a patient suffering from diabetes or abnormal glucose tolerance) is also concomitantly in a state of fatigue as a result of the bodily stress caused by suffering from the disclosed ailments. Thus, the subject(s) of the copending claims meets the subject required by the instant claims (i.e., "animals in the state of fatigue"; see, e.g., instant claims 28-29) and, therefore, the coenzyme Q composition must necessarily possess the same fatigue reducing effects when administered to the subject(s) of the copending claims, whether recognized by the applicant or not, because products of identical chemical composition cannot exert mutually exclusive properties when used in the same manner (i.e., same composition, same host, same amount, etc.) under the same circumstances.

In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same agents, same amounts, etc.) for use in the same subject (i.e., in this case, an animal in a state of fatigue), the fatigue-reducing property that Applicant discloses and/or claims is necessarily present. Please reference MPEP §2112.

Furthermore, with regard to instant claim 35, which is directed to the administration of the claimed coenzyme formulation to "middle aged or older persons", the patented claims broadly teaches the use of the disclosed coenzyme Q formulation for use in patients or persons *per se* and, thus, places the treatment of any human at any stage of development (i.e., "young", "middle aged" or "older"), within the possession of the public.

Accordingly, rejection of claims 28, 30 and 32-35 is proper over claims 9-12 of U.S. Patent Application No. 10/505,523 as claiming obvious and unpatentable variants thereof.

Claims 28-36 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over, alternatively, claim 5 of U.S. Patent No. 6,184,255 or claims 3-16 of U.S. Patent No. 7,015,252, in view of Merriam-Webster Collegiate Dictionary (1996; p.424).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

The claims of the '255 patent are directed to the treatment of a patient suffering from coenzyme Q10 deficiency by oral administration of an effective amount of a composition comprising coenzyme Q10

(understood to be the "oxidized" coenzyme Q10 as in instant claim 29) in combination with a reduced coenzyme Q10.

The claims of the '252 patent are directed to methods for lessening or reducing oxidative stress in vivo, particularly wherein the oxidative stress is associated with a disease (such as, *inter alia*, cerebral ischemia, renal disease, progeria, skin disease, etc.), comprising administering a reduced coenzyme Q compound of a formula identical to that claimed as instant formula (1), which may also be in combination with an oxidized coenzyme Q compound of a formula identical to that claimed as instant formula (2). The patented claims clearly provide for the use of either the oxidized or reduced form of coenzyme Q10, since each formula provides for n to be from 1-12, as well as for "external" application (understood to be to the skin as instantly claimed; see patented claim 16).

Merriam-Webster is cited as evidence to define the term "fatigue" as used in the instant claims as "a weariness or exhaustion from labor, exertion or stress" (p.424).

In view of the fact that the term "fatigue" is defined as a weariness or exhaustion from, *inter alia*, stress, and further in view of the fact that any disease or disorder, including the various diseases (such as, e.g., coenzyme Q deficiency, cerebral ischemia, renal disease, progeria, skin disease, etc.) disclosed in the patented claims, causes bodily stress, it necessarily follows that the subject (s) treated via the method(s) disclosed in the patented claims (e.g., a patient suffering from coenzyme Q deficiency, cerebral ischemia, renal disease, progeria, skin disease, etc.) is also concomitantly in a state of fatigue as a result of the bodily stress caused by suffering from the various disclosed ailments. Thus, the subject(s) of the patented claims meets the subject required by the instant claims (i.e., "animals in the state of fatigue"; see, e.g., instant claims 28-29) and, therefore, the coenzyme Q composition must necessarily possess the same fatigue reducing effects when administered to the subject(s) of the patented claims, whether recognized by the patentee or not, because products of identical chemical composition cannot exert mutually exclusive properties when used in the same manner (i.e., same composition, same host, same amount,

etc.) under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same agents, same amounts, etc.) for use in the same subject (i.e., in this case, an animal in a state of fatigue), the fatigue-reducing property that Applicant discloses and/or claims is necessarily present. Please reference MPEP §2112.

Furthermore, with regard to instant claim 35, which is directed to the administration of the claimed coenzyme formulation to "middle aged or older persons", the patented claims broadly teaches the use of the disclosed coenzyme Q formulation for use in patients and/or humans *per se* and, thus, places the treatment of any human at any stage of development (i.e., "young", "middle aged" or "older"), within the possession of the public.

Accordingly, rejection of claims 28-36 is proper over claim 5 of U.S. Patent No. 6,184,255 or claims 3-16 of U.S. Patent No. 7,015,252 as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 28-37 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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December 11, 2008

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